

OFFERING INCENTIVES FOR RESEARCH PARTICIPATION

Definition of Incentives

Etymology: Middle English, from Late Latin *incentivum*, from neuter of *incentivus* stimulating, from Latin, setting the tune, from *incentus*, past participle of *incinere* to play (a tune), from *in-* + *canere* to sing — Date: 15th century

"something that incites or has a tendency to incite to determination or action"

Ethical Issues

Offering incentives for research participation is often a contentious issue. Some argue that research subjects should not be treated as a commodity that is bought and sold. Others argue that respect for autonomy means that subjects retain the right to exercise free choice in judging the acceptability of risk and weighing the benefits of research participation. Further, in this view, offering incentives is a means of showing appreciation for the time and effort required of subjects.

The role of IRBs in making decisions regarding subject incentives may be equally contentious. Should IRBs limit their review to the consent process, ensuring that it is fully informed? Or should the IRB protect potential subjects from inducements that may affect their ability to make an informed, voluntary choice? Is the latter not paternalism? As with many aspects of human subjects review, plans to offer incentives should be evaluated on a case-by-case basis.

Some incentives, particularly large payments for participation in clinical trials, may result in an unequal distribution of the burdens and risks of research. Individuals who are unemployed or who lack access to health care or insurance may be more likely to agree to participate in research with higher risks, but no potential direct benefit, for simple economic reasons. Incentives may have a direct bearing on considerations of justice, e.g., fair distribution of the risks and benefits of research participation.

Some also argue that it is unethical to offer incentives to individuals who in their view would use it in "inappropriate" ways. This issue may come up during reviews of studies which propose to recruit and offer incentives to persons who abuse drugs or alcohol. IRBs may wish to protect subjects from themselves, and thus risk losing sight of the principal of autonomy and respect for persons, a basic ethical tenet of the Belmont Report.

Federal Regulations

Neither the HHS or FDA regulations provide specific limits on incentives for research subjects. HHS regulations state that "...investigators shall seek consent only under circumstances ... that minimize the possibility of coercion or undue influence" (45 CFR 46.116).

The Office for Human Research Protections does not define "undue influence" with any precision: "Clear cases of coercion (*i.e.*, actual threats) are readily identifiable; it is more difficult to recognize undue inducement. An offer one could not refuse is essentially coercive (or

"undue"). Undue inducements may be troublesome because: (1) offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and (2) they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling — or continuing — as participants in a research project".

What Incentives **Are Not**

☞ Incentives should not be considered as "benefits" of research participation.

Purpose of Incentives

Incentives are permitted in research as a way to encourage participation, to increase the possibility of continued participation in longitudinal research, and to compensate subjects for potential burdens of research participation, such as time, inconvenience, travel, etc.

Incentives may take the form of:

- Cash
- Gift cards (coffee, groceries, etc.)
- Phone cards
- Small gifts (hats, diapers, pens, toys for small children, etc.)
- Candy bars or snacks
- Bus passes or tokens
- Debit cards
- Cash in an institutional account (hospital or prison settings)
- Bank drafts or checks
- Lotteries

How Much Is *Too Much*?

Some study subjects participate in research simply for the money. Recent articles about "guinea-pigging" point out that there is now a cottage industry of "professional" research subjects who choose to participate in multiple clinical trials, one after the other, solely for financial gain. Potential risks or harms of untested drugs or biologics are secondary, at best.

Incentives, whatever the form, should be *commensurate with the time required for research procedures* and commitment to the study timelines. Consider: what is the potential impact of offering \$100 cash for a 15-minute interview about shopping habits?

It is also important to consider the *study population* for whom incentives are offered. A fifty dollar gift card may be appropriate for an adult participating in a two-hour interview for which he/she had to travel to a research site. The same amount offered to a young child could result in a parent pressuring the child to agree to research participation, or the parent taking the money intended for the child.

The *form* of the incentive should also be appropriate to the study population. Offering checks that need to be cashed may not be appropriate for persons unlikely to have a bank account. Offering "high value" items in prison setting could create undue influence and disruption within the institution in terms of internal exchanges of goods for favors. Researchers may offer several options with the same monetary value, for example, the choice of a gift card for Wal-Mart, Fred Meyer, or Toys 'R Us.

When Should Subjects Receive Incentives?

In general, incentives should be prorated over the course of the research, regardless of the level of completion. For studies involving multiple data collection intervals or multiple procedures, incentives may be provided at each interval or procedure. Payment of incentives should not be contingent upon the subject completing the entire study. However, it may be appropriate to offer a small "bonus" for completing the study.

Some incentives may be provided *before* the subject enrolls in the research. Some mail surveys send a modest incentive (worth less than \$5) along with a survey, to encourage participation. In this case, the subject may keep the money, even if he/she decides not to participate.

Incentives for Children

Depending on their age and developmental level, incentives offered to children may create undue influence to agree to research participation -- or be totally uninteresting. Very young children may not understand the value of money, while a stuffed toy or picture book could be appealing. Adolescents may be easily swayed by cash, gift cards, or iPods to the point of not sufficiently considering risks of research participation. Then, too, IRBs must consider *to whom* an incentive is provided: the parent and/or the child subject. Incentives offered for a child's participation should be provided in such a way that undue influence is unlikely to occur for either the parent or the child.

Issues to Consider:

- ✓ Has the researcher overemphasized incentives in recruitment and consent materials?

Incentive payments are often presented prominently, at the beginning of a letter or near the top of a flyer, in bold or larger font than the rest of the text.

Exclamation marks may be used to increase "excitement".

Sometimes researchers employ the "come on" approach: "You could win \$75 just for contacting the researchers! Call today!"

- ✓ Is the amount (incremental and total) reasonable in relation to what the subject is asked to do and the time required?
- ✓ When would subjects receive incentives?

Is the researcher proposing to withhold all incentives until the subject completes all research procedures?

Is there a "bonus" for completing all research procedures?

What incentives would subjects receive if they withdraw from the study before completion?

- ✓ Are there sufficient funds in the study budget to pay all promised incentives over the life of the study?

- ✓ Are some subjects offered larger or more frequent incentives than others? Are comparison or control subjects offered incentives, while intervention subjects are not?
- ✓ Is the payment of incentives adequately described in the consent process, including timing, amounts, and any bonus payments for completion?

Sources:

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